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EXAMINER	
SAUNDERS, D	
ART UNIT	PAPER NUMBER
1644	16

DATE MAILED: 10/23/01

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☒ is extended to run 6 MOS or continues to run \_\_\_\_\_ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).
- ☒ Applicant's response to the final rejection, filed 10/9/01 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- ☒ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
  - ☒ They raise new issues that would require further consideration and/or search. (See Note).
  - ☒ They raise the issue of new matter. (See Note).
  - ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: SEE ATTACHMENT

2. ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.
3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: \_\_\_\_\_  
Claims objected to: \_\_\_\_\_  
Claims rejected: 1-9, 11-20

However;

- ☐ Applicant's response has overcome the following rejection(s): \_\_\_\_\_

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because SEE ATTACHMENT

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other IDS WILL NOT BE CONSIDERED

Art Unit: 1644

The amendment of 10/9/01 would raise new issues and considerations requiring a further search; also, issues of new matter would be raised, since the nature of the invention would be changed in at least the following ways:

- 1) What is being tested has been changed from "an antigen comprising a T-cell epitope" (original claim 9) to merely a "T cell epitope", which need not be antigenic.
- 2) The composition(s) being tested now have "a defined T-cell epitope". Nothing in the previous considerations required that this be "defined". At the start of the method.
- 3) The claims now require comparison "to a predetermined level" of T cell response. Nothing in the previous considerations required that the response be related to a "predetermined level".

The arguments pertaining to use of human APCs and T-cells and to the use of defined T-cell epitopes in a vaccine composition would not overcome the prior art. The combination of prior art references cited provided adequate motivation to use T-cell epitopes identified by screening in vaccine compositions for human use and provided adequate motivation to test such with human cells. See, for example, Paper 9 at page 4.

The IDS of 10/9/01 will not be considered, since there is no statement under 37 CFR 1.97(e).

Any inquiry concerning this communication should be directed to D. Saunders at telephone number (703) 308-3976.

Typed 10/22/01

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ART UNIT 182 *1644*